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In the Supreme Court of the United States

OCTOBER TERM, 1942

No. 266

RESEARCH LABORATORIES, INC., PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINION BELOW

The opinion of the circuit court of appeals (R. 60–66) is reported at 126 F. (2d) 42.

JURISDICTION

The judgment of the circuit court of appeals was entered February 24, 1942 (R. 66–67). A petition for rehearing was denied April 2, 1942 (R. 67). On June 26, 1942, the time for filing a petition for a writ of certiorari was extended to August 1, 1942, by order of Mr. Justice Douglas. The petition for a writ of certiorari was filed July 30, 1942. The jurisdiction of this Court is invoked under Section 240 (a) of the Judicial Code, as amended by the Act of February 13, 1925.

QUESTION PRESENTED

Whether misleading circulars "accompany" a drug within the meaning of the Federal Food, Drug and Cosmetic Act, which defines "labeling" as including "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article," when they are shipped in interstate commerce from the same point of origin, arrive simultaneously at the same destination, and are displayed with the drug in retail stores.

STATUTE INVOLVED

The pertinent provisions of the Federal Food, Drug and Cosmetic Act (Act of June 25, 1938, ch. 675, 52 Stat. 1840); are:

Section 304 (21 U. S. C. 334 (a)):

> (2) Any article of * * * drug * * * that is * * * misbranded when introduced into or while in interstate commerce, * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found:
> * * *

Section 502 (21 U. S. C. 352):

> A drug or device shall be deemed to be misbranded—
> (a) If its labeling is false or misleading in any particular.

Section 201 (21 U. S. C. 321):

> For the purposes of this chapter—
>
> * * * * *
>
> (m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

STATEMENT

Pursuant to Section 304 of the Federal Food, Drug, and Cosmetic Act, *supra,* a libel was filed in the District Court for the Western District of Missouri for the condemnation of 143 packages of a drug called "Nue-Ovo" (R. 12–16). Petitioner, the manufacturer of the article, was permitted to intervene in the proceeding (R. 6–12) and obtained removal of the cause to the District Court for the Western District of Washington (R. 1–6). Exceptions to the libel were filed by petitioner and allowed by the district court (R. 17–19), whereupon the Government filed an amended libel (R. 19–23). Exceptions to the amended libel were then filed (R. 23–24) and on June 2, 1941, the court dismissed the action on the ground that the amended libel failed to allege facts sufficient to state a cause of action (R. 25–26). A motion by the Government for leave to file a second amended libel (R. 29–35) was denied (R. 45–46). On appeal, the circuit court of appeals reversed the judgment dismissing the amended libel (R. 60–67).

The amended libel (R. 19–23) alleged that 143 packages each containing 3 bottles of Nue-Ovo were shipped in interstate commerce from Chicago to the Crown Drug Company at Kansas City, Missouri. A shipment of circulars entitled "What is Arthritis" was also shipped from Chicago and was received by the Crown Drug Company "simultaneously with the said article." (R. 21). These circulars (R. 15–16) "create the impression in the mind of the reader thereof that the said article is a competent treatment for Arthritis * * * whereas the said article is not" (R. 20). The circulars were then distributed along with the drug to three of the Crown Company's retail drug stores "and were prominently displayed in the said retail drug stores in the same rooms and in close proximity to said packages of 'Nue-Ovo'" and were distributed to "members of the public who appeared in said drug stores" (R. 22).[1]

ARGUMENT

A "misbranded" drug subject to condemnation may be one which has a false or misleading "labeling," which is defined by the Federal Food,

[1] It appears from the second amended libel (R. 29–35), which the court denied leave to file (R. 45–46), that the labels on the bottle and its package contained the name "Nue-Ovo" and dosage directions, but omitted altogether any statement as to the ailments or diseases it was designed to cure. Hence without the circulars, the medicine was nothing except liquid in bottles for a purpose unknown.

Drug and Cosmetic Act, *supra,* as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." Petitioner contends that under this definition a circular is not "accompanying" an article unless it is contained within the article's package (Br. 10–21). We think it is plain, however, both from the legislative history of the Act and from the plain meaning of the words "accompanying such article" that Congress did not intend that the definition should be so narrowly construed.

The Food and Drug Act of 1906, as amended, provided that a drug was to be deemed misbranded "If its package or label shall *bear or contain* any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent" (italics supplied) (Act of August 23, 1912, 37 Stat. 416). The word "contain" was inserted by amendment in 1912 to cover circulars or printed matter placed inside the package (*Seven Cases* v. *United States,* 239 U. S. 510, 515).[2]

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[2] The Food and Drug Act of 1906 originally applied the term "misbranded" to "the package or label of [a drug or article of food] which shall *bear* any statement, design, or device regarding such article * * * which shall be false or misleading in any particular * * *" (italics supplied) (34 Stat. 768, 770) and this language was held inap-

In 1933, a new food and drug bill (S. 1944, 73d Cong., 1st Sess.), also covering cosmetics, was introduced in the Senate by Senator Copeland (77 Cong. Rec. 5721) and was replaced (78 Cong. Rec. 59) by another bill (S. 2000, 73d Cong., 2d Sess.), which in turn was superseded by a third bill (S. 5, 74th Cong., 1st Sess.; 79 Cong. Rec. 100). Consideration of these bills extended over a period of five years, the purpose of Congress being to cover loopholes and inadequacies in the existing law and to amplify and strengthen provisions designed to safeguard the public health and prevent deception.[3] In all of the bills and their numerous revisions, the existing definition of a "misbranded" drug as one whose package or label shall *bear or contain* any false or fraudulent statement, was supplanted, *inter alia,* by the provision that a drug or device shall be deemed to be misbranded "If its labeling is false or misleading in any particular" and that "The term 'labeling' includes all labels and other written, printed, and graphic matter, in any form whatsoever, *accompanying* any food, drug, or cosmetic" (italics supplied) (see 79 Cong. Rec. 4849, 4859,

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plicable to false or misleading circulars enclosed in the package with the article (*United States* v. *American Druggists' Syndicate*, 186 Fed. 387, 391 (E. D. N. Y.)).

[3] See S. Rep. No. 646, 74th Cong., 1st Sess., p. 1; H. Rep. No. 2755, 74th Cong., 2d Sess., pp. 1–3; S. Rep. No. 152, 75th Cong., 1st Sess., p. 1; S. Rep. No. 91, 75th Cong., 1st Sess., p. 1; H. Rep. No. 2139, 75th Cong., 3d Sess., pp. 1–2; 79 Cong. Rec. 4262.

8351; 80 Cong. Rec. 10230, 10514). At no time during the debates in Congress or in the House and Senate reports on the bills was any specific discussion had as to the reason for the new definition. It is true that there is an inference in one of the committee reports to the effect that the word "labeling" was designed to include circulars contained in the package or article.[4] There is nothing to indicate, however, that it was intended that the definitions given were intended to include only such circulars. On the contrary, Senator Copeland assumed a broad interpretation of the word "accompanying," stating that "No one questions * * * that the Food and Drug Administration * * * shall pass upon the material which goes with the package" (79 Cong. Rec. 5023). Similarly, the Chief of the Food and Drug Administration interpreted the proposed definition of the term "labeling," supra, "to include not only the label *but all circulars and plac-*

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[4] Thus in S. Rep. No. 646, 74th Cong., 1st Sess., upon which petitioner relies (Br. 15), it is stated (p. 2):

"The differentiation between label and labeling is necessary because the declarations of certain facts for the information and guidance of consumers required by the bill should, to accomplish their purpose, appear on the principal label or labels where they can be easily observed, rather than on side panels of the labeling or in circulars within the package where they may escape notice."

The language quoted by petitioner in the second paragraph of his brief on page 15 obviously refers to interpretation of the words "false or misleading in any particular," rather than to the term "labeling."

ards for display purposes and the like that may in any form whatsoever accompany the article." (Italics supplied.) Hearings on S. 1944 before subcommittee of the Senate Committee on Commerce, Dec. 7 and 8, 1933, 73d Cong., 2d Sess.

The proposed definition was revised to its present form in conference by omitting only the words "in any form whatsoever" (see 83 Cong. Rec. 7788, 9087–9088; H. Rep. No. 2716, 75th Cong., 3d Sess.) with no further explanation than that there were many minor changes in the bill and that "all of them were the result of careful attention given by the House Committee for the purpose of improving, balancing, and strengthening the bill" (83 Cong. Rec. 9095).

The bills also sought to give jurisdiction over false advertisements to the Food and Drug Administration on the premise that advertising was "an extension of labeling" (Pet. 15–16; 79 Cong. Rec. 5022–5023; S. Rep. No. 152, 75th Cong., 1st Sess., p. 3). The term "advertisement" was defined as including "all representations of fact or opinion disseminated in any manner or by any means *other than by the labeling,* for the purpose of inducing, directly or indirectly, the purchase of food, drugs, devices, or cosmetics" (italics supplied) (see 79 Cong. Rec. 5021; 80 Cong. Rec. 10230, 10514; 81 Cong. Rec. 2003). Much controversy arose on the question whether the Food and Drug Administration or the Federal Trade Commission

should have jurisdiction over advertising, and it is clear from the debates in this connection that members of Congress were concerned only about newspaper, magazine and radio advertising (see 79 Cong. Rec. 4916, 4918, 5021, 5024–5025, 5140, 5216–5217; 80 Cong. Rec. 10241, 10243, 10675, 10677–10679; 81 Cong. Rec. 2005–2006; 83 Cong. Rec. 7899–7900).[8]

It therefore does not appear that Congress had any intention to restrict the word "accompanying" to false or misleading matter contained in the article's package or to give the Federal Trade Commission jurisdiction over false or misleading matter that goes with an article, as petitioner contends. Congress was enacting a law designed to cover the loopholes and inadequacies of the Food and Drug Act of 1906, as amended, and in doing so rejected the specific words "bears or contains," which appeared in the old Act and which compel

[8] Ultimately, the advertising provisions were taken out of the food and drug bill (cf. 83 Cong. Rec. 7788–7790, 7795–7797) and were placed in the Act of March 21, 1938, amending the Act creating the Federal Trade Commission (S. 1077, 75th Cong., 1st Sess., 52 Stat. 111, 114–117; 15 U. S. C. 52–56, inc.). This Act defines the term "false advertisement" as "an advertisement, *other than labeling*, which is misleading in a material respect; * * *" (italics supplied) (15 U. S. C. 55 (a)) which plainly does not interfere with the jurisdiction of the Food and Drug Administration over false advertising which "accompanies" the article. Petitioner impliedly concedes this to be true (Pet. 16) for he argues that the circulars in question are advertising only because they did not "accompany" the article, i. e., were not contained "within the package."

the interpretation for which petitioner contends, and replaced them by the broader language of "(1) upon any article or any of its containers or wrappers, or (2) accompanying such article." Certainly, Congress could not have intended that the Act might be circumvented by the simple expedient of using "accompanying" circulars to convey false or misleading information to the purchasing public, instead of placing that information on the article or in its package. Cf. *Austin* v. *Tennessee,* 179 U. S. 343, 361.

Full effect should therefore be given to the phrase "accompanying such article," which plainly means more than "contained in" the package of the article. As this Court has stated, no single argument has more weight in statutory interpretation than the plain meaning of the words of the statute. *Browder* v. *United States,* 312 U. S. 335, 338; see also, *United States* v. *American Trucking Associations, Inc.,* 310 U. S. 534, 543. The "courts are not free to reject that meaning" where no absurd result or obvious thwarting of the statute follows "and where, as here, it appears to be consonant with the purposes of the Act as declared by Congress and plainly disclosed by its structure." *Helvering* v. *Hammel,* 311 U. S. 504, 510–511; cf. *United States* v. *Rosenblum Truck Lines,* 315 U. S. 50, 55.

Finally, that the circulars entitled "What is Arthritis" accompanied the 143 packages of Nue-

Ovo in interstate commerce, as required by the Act, seems clear. The circulars were shipped in interstate commerce and received with the articles at the warehouse of the Crown Drug Company, placed in the same room with the packages for distribution to the three retail stores of the Crown Drug Company, and prominently displayed in those stores in proximity to the packages.[6] Since the circulars and packages were in interstate commerce until they were placed together in the same room for distribution, if not longer,[7] the circulars accompanied the packages in interstate commerce, as the court below held (R. 64–65), and constituted a misbranding which rendered the 143 packages of Nue-Ovo subject to seizure under the provisions of 21 U. S. C. 334 (a) (*supra*, p. 2).[8]

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[6] Petitioner admits that *generally speaking*, "circulars, booklets or pamphlets accompany an article when shipped together, although in separate packages," but claims that they do not accompany an *article* when the two are shipped in separate containers traveling in different trains, trucks, or other vehicles (Br. 20–21). This is obviously a distinction without any substantial difference.

[7] See *Pacific States Co.* v. *White*, 296 U. S. 176, 184; *Schechter Corp.* v. *United States*, 295 U. S. 495, 543; *Weeks* v. *United States*, 245 U. S. 618, 622; *McDermott* v. *Wisconsin*, 228 U. S. 115, 135; *Leisy* v. *Hardin*, 135 U. S. 100.

[8] Petitioner also asserts that a Federal Trade Commission proceeding, the nature of which is not disclosed in petitioner's brief or in the record, is *res judicata* with respect to the question of whether the circulars entitled "What is Arthritis" are a "labeling" or an "advertisement" (Br. 21–23). We are advised by the Federal Trade Commission that no formal complaint has ever been issued by the Commission involving

CONCLUSION

The case was correctly decided below and presents no conflict of decisions or other question warranting review by this Court. We therefore respectfully submit that the petition for a writ of certiorari should be denied.

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AUGUST 1942.

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the product "Nue-Ovo" and that petitioner apparently has reference to a matter which is not of public record—an investigation conducted on an application for the issuance of a complaint. There was, therefore, no "proceeding" against petitioner and the doctrine of *res judicata* is, for that reason alone, inapplicable.

U. S. GOVERNMENT PRINTING OFFICE: 1942